

External Quality Assessment Scheme

Gastric biomarkers Round 1, 2022

Specimens

Please find enclosed two lyophilized samples S001 and S002.

Caution

Quality control specimens derived from human blood must be handled with the same care as patient samples, i.e. as potential transmitters of serious diseases. The specimens are found to be HBsAg, HCVAb and HIVAgAb negative when tested with licensed reagents, but no known test method can offer complete assurance that the specimens will not transmit these or other infectious diseases.

Background information

Specimen S001:

Protein-stimulated blood sample from a 68-year-old old woman with epigastric pain and postprandial symptoms for 14 months. Manifests also iron-deficiency anemia. No previous eradication of *H. pylori*, no PPI medication, occasional use of NSAIDs.

Specimen S002:

Fasting blood sample from a 66-year-old man with dyspeptic pain for three years. No previous eradication of *H. pylori*, use of PPI medication, but now a 5- day break, occasional use of NSAIDs.

Examinations

Gastrin 17
Pepsinogen I,
Pepsinogen II
H. pylori antibodies (HPAbG)

Storage and use

Samples S001 and S002 are lyophilized samples. Store the samples in a refrigerator at 2... 8 ° C. Add 3.0 ml of reagent-free water to the lyophilized samples and allow to dissolve for 30 min. Rotate the sample gently but avoid foam formation. Ensure solubility and homogeneity. The samples must be analyzed immediately after dissolving the sample. The dissolved sample cannot be frozen and not reanalyzed.

Analyze each sample as a patient sample.

Result reporting

Log in to LabScala (www.labscala.com) with your username and password. Please fill in your contact information, sample arrival date and sample storage questions. Proceed from one page to another with the green buttons. On the result sheet please select your method from the dropdown menu and fill in your result to the result field. There is also a question about the software you used for the clinical interpretation of each case. Please select the software name from the dropdown menu and the clinical interpretation from another dropdown menu.

Three different result sets per sample can be reported in LabScala (www.labscala.fi). The method may be the same or different. When reporting multiple results, please note that in the report each result reported with same method always corresponds to the result position in LabScala eform.

If you have any questions, please contact the EQA coordinator.

2022-06-06

INSTRUCTIONS

Product no. 2753
LQ751722011-012/NO

If the kit is incomplete or contains damaged specimens, please report immediately to info@labquality.fi

The results should be reported no later than **June 27, 2022.**

Inquiries

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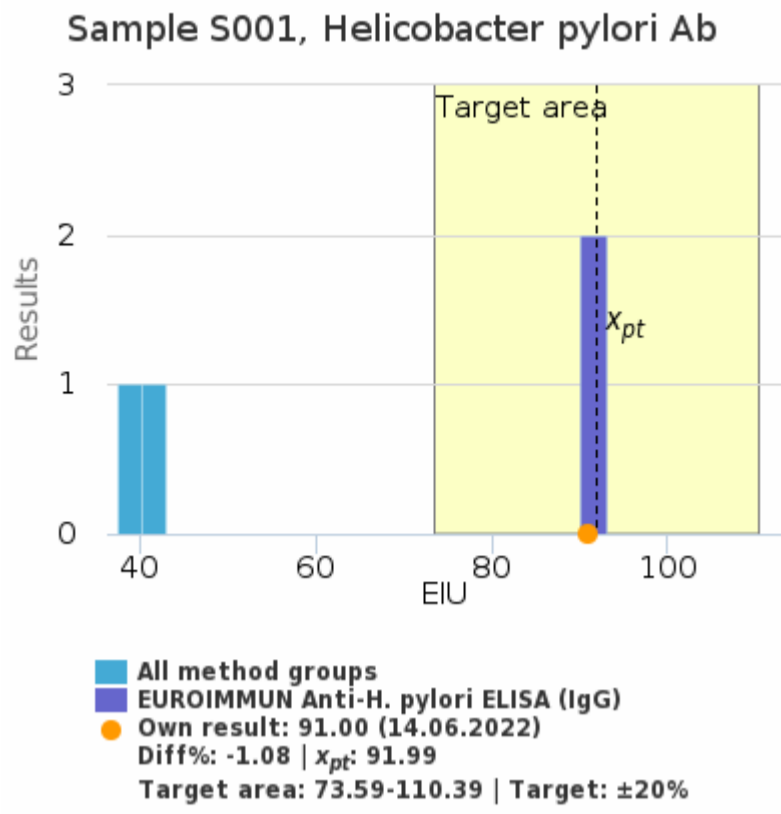
S001



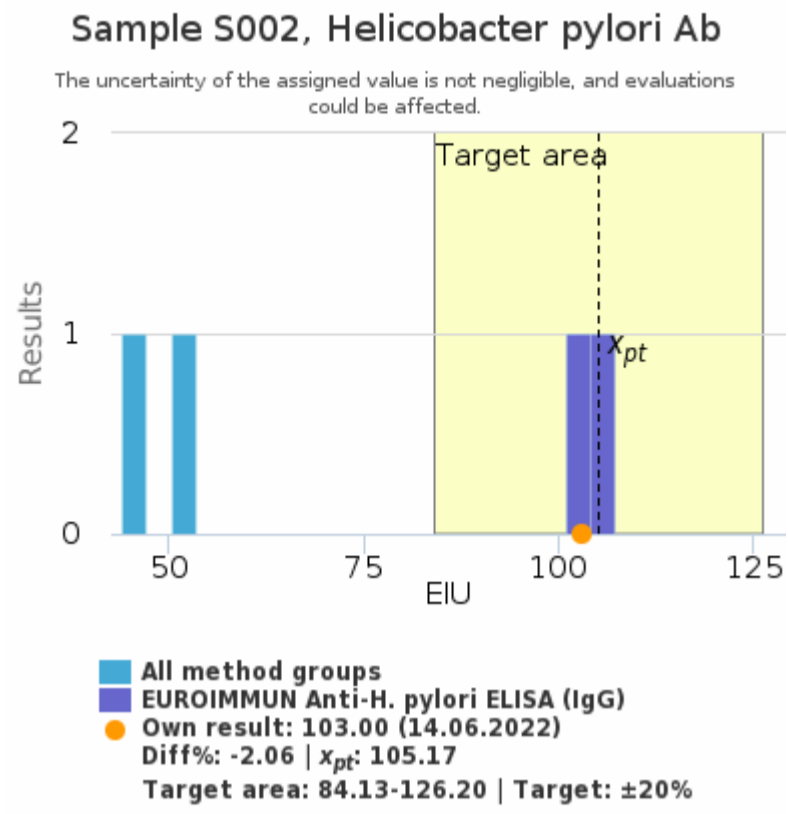
S002



Helicobacter pylori Ab [1]



	x_{pt}	sd	SEM	CV%	n
EUROIMMUN Anti-H. pylori ELISA (IgG)	91.99 EIU	1.40	0.99	1.5	2
All methods	65.96 EIU	30.13	15.07	45.7	4



	x_{pt}	sd	SEM	CV%	n
EUROIMMUN Anti-H. pylori ELISA (IgG)	105.17 EIU	3.06	2.17	2.9	2
All methods	76.84 EIU	32.96	16.48	42.9	4



Round	Sample	x_{pt}	Result	diff%	z-score
22/1	Sample S002	105.17	103.00	-2.06%	-
22/1	Sample S001	91.99	91.00	-1.08%	-
21/1	Sample S002	-	99.00	-	-
21/1	Sample S001	-	93.00	-	-

Report info**Participants**

5 participants from 4 countries.

Report info

Your own result should be compared to others using the same method.

Assigned values (x_p , target values) are means of the results where results deviating more than ± 3 standard deviation from the median are removed. The standard uncertainty (u) of

the assigned value is reported as standard error of the mean (SEM). Additionally, if the measurement uncertainty of the target value is large an automatic text is printed on the report: "The uncertainty of the assigned value is not negligible, and evaluations could be affected."

In case the client's result is the only one in the method group, no assigned value will be calculated, no target area shown, and no statistics calculated. In case there are only a few results in the client's own method group, the result can be compared to all method mean or to a group that is similar to the own method.

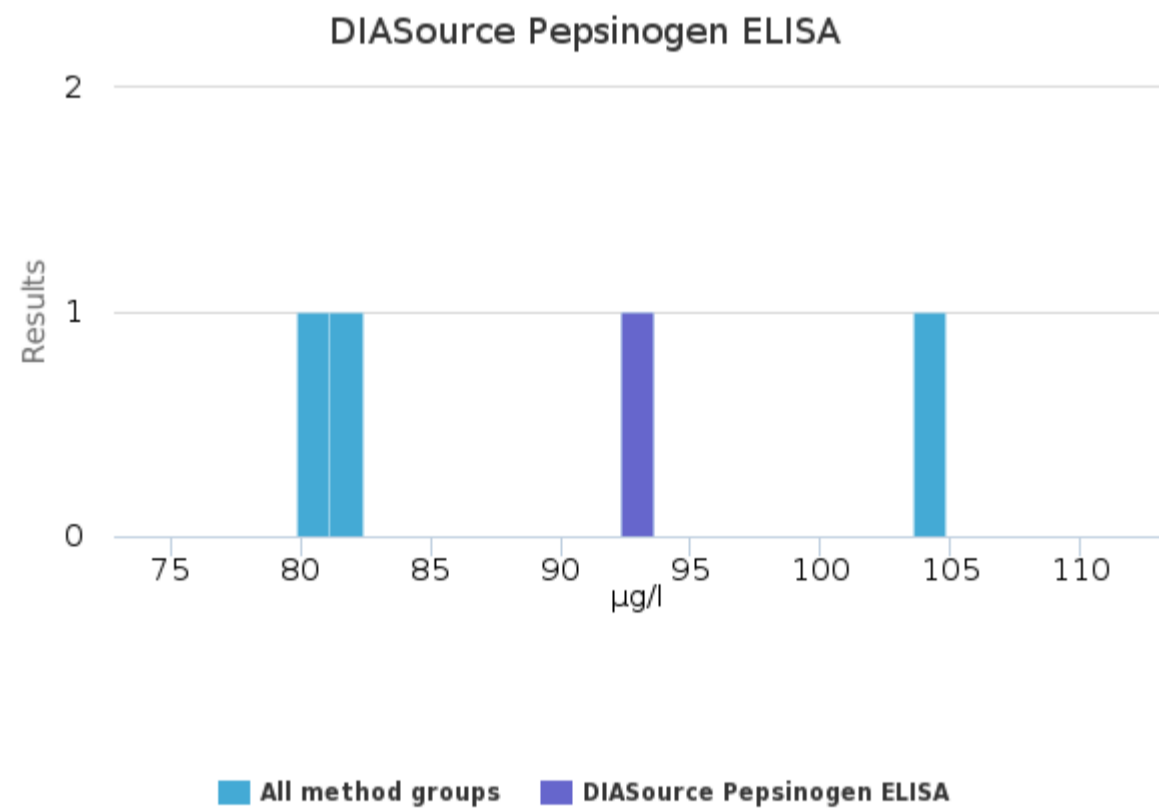
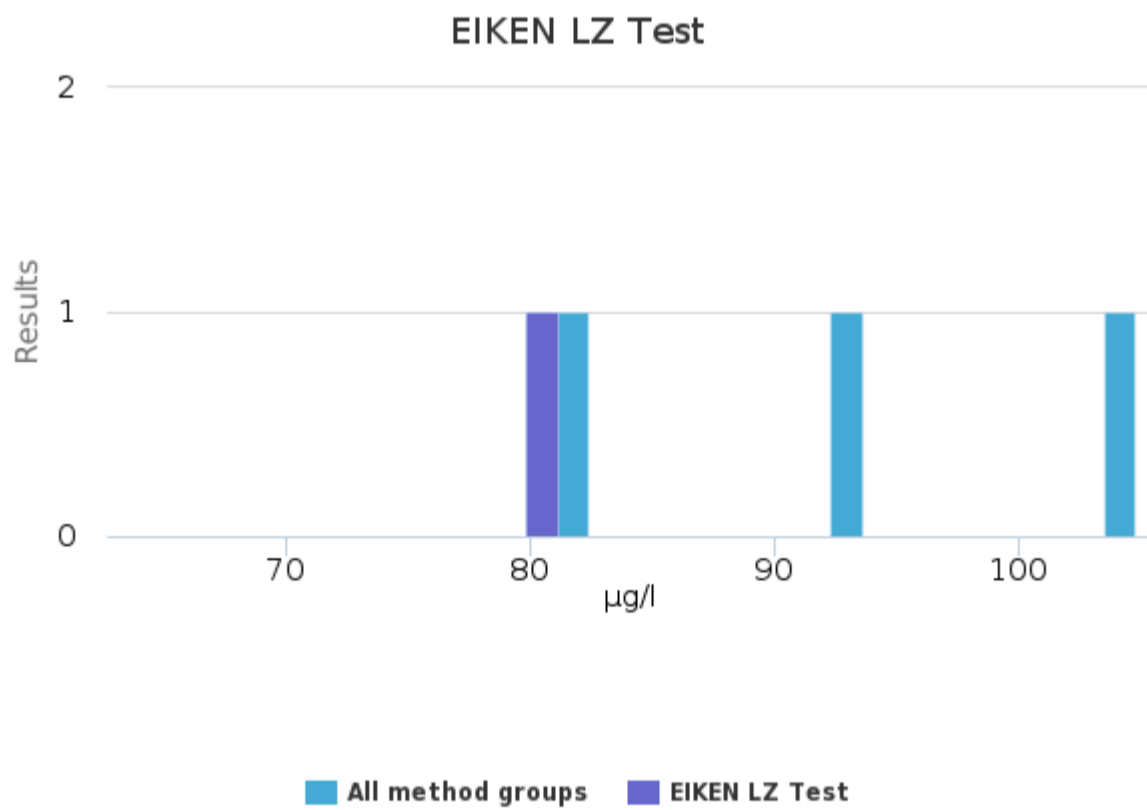
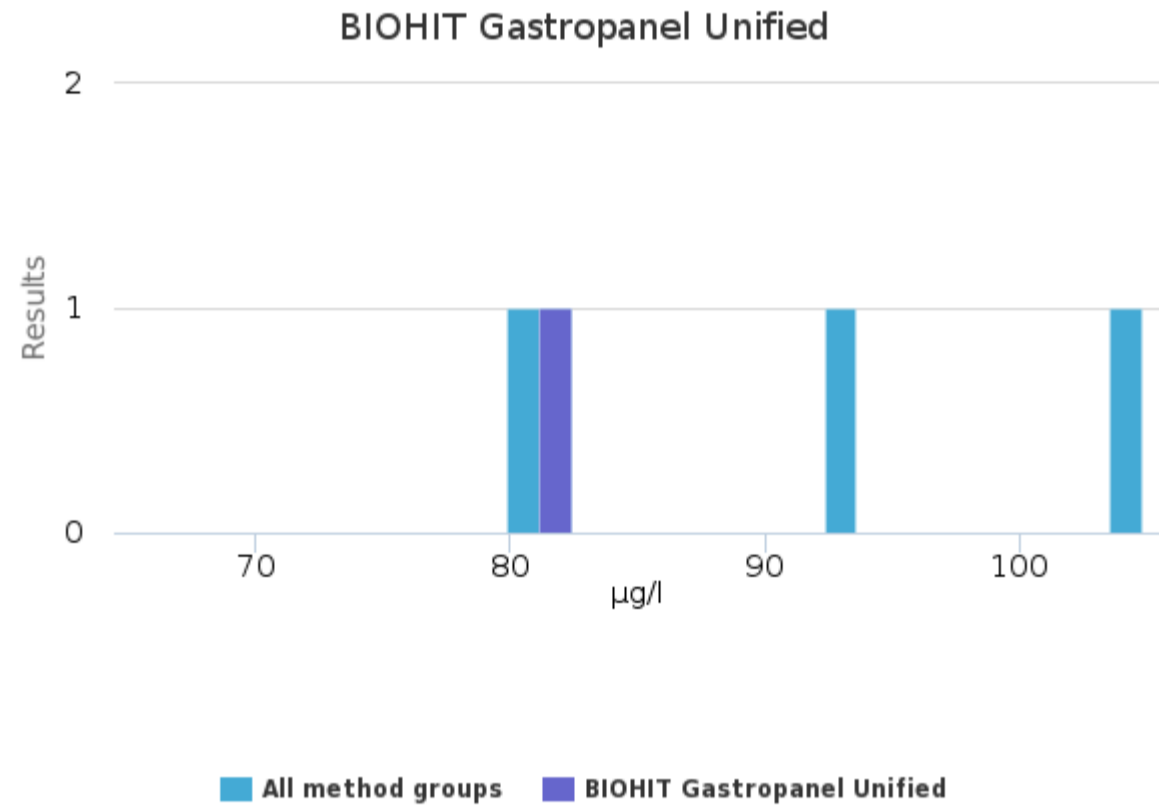
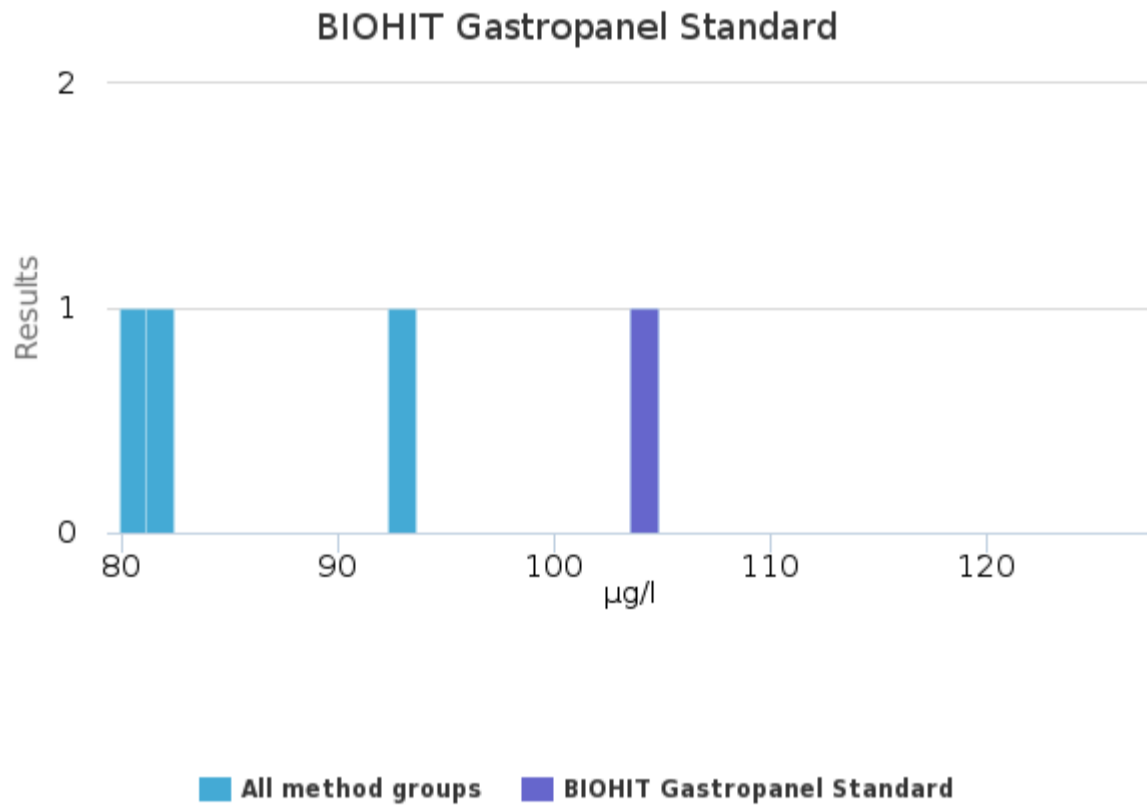
Results reported with $<$ or $>$ -signs cannot be included in the statistics.

For information on report interpretation and performance evaluation, please see the "EOAS Interpretation guidelines" LabScala User instructions (top right corner ?Help link).

Sample S001 | Pepsinogen I, µg/l

Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
BIOHIT Gastropanel Standard	-	-	-	-	-	104.80	104.80	-	1
BIOHIT Gastropanel Unified	-	-	-	-	-	82.11	82.11	-	1
EIKEN LZ Test	-	-	-	-	-	79.89	79.89	-	1
DIASource Pepsinogen ELISA	-	-	-	-	-	92.70	92.70	-	1
All	89.88	87.41	11.41	12.7	5.71	79.89	104.80	-	4

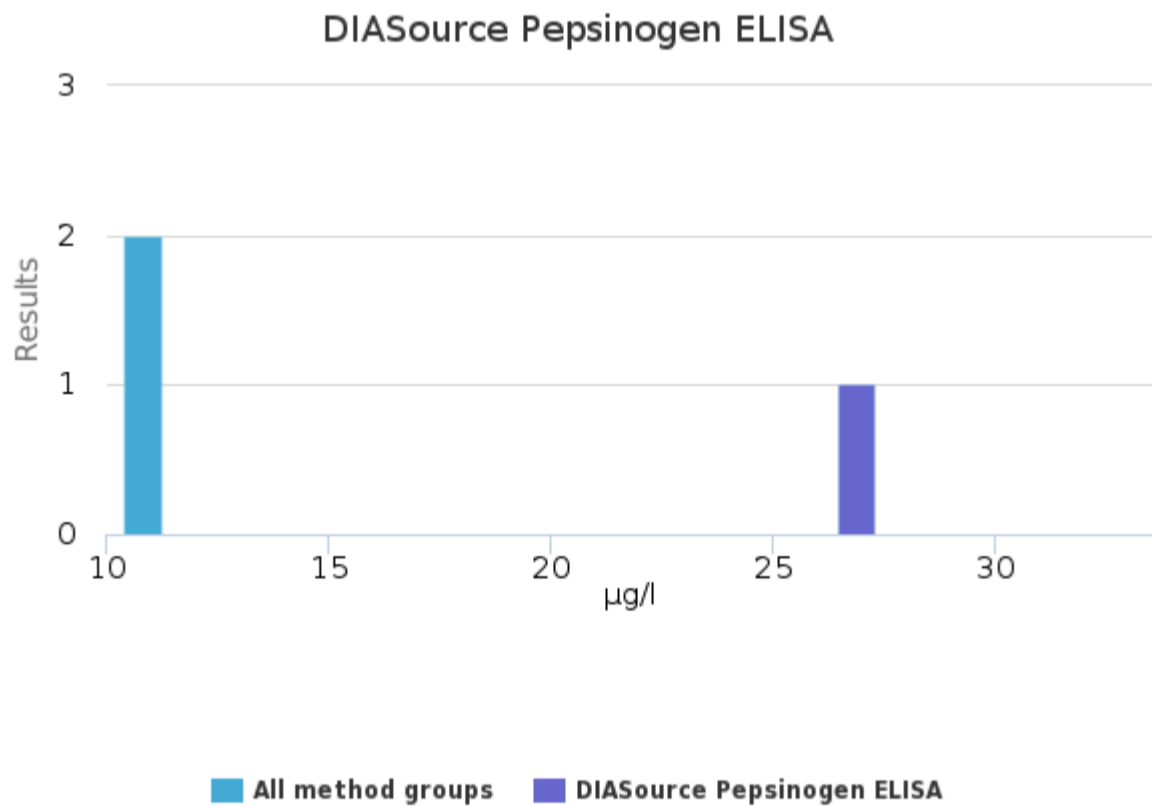
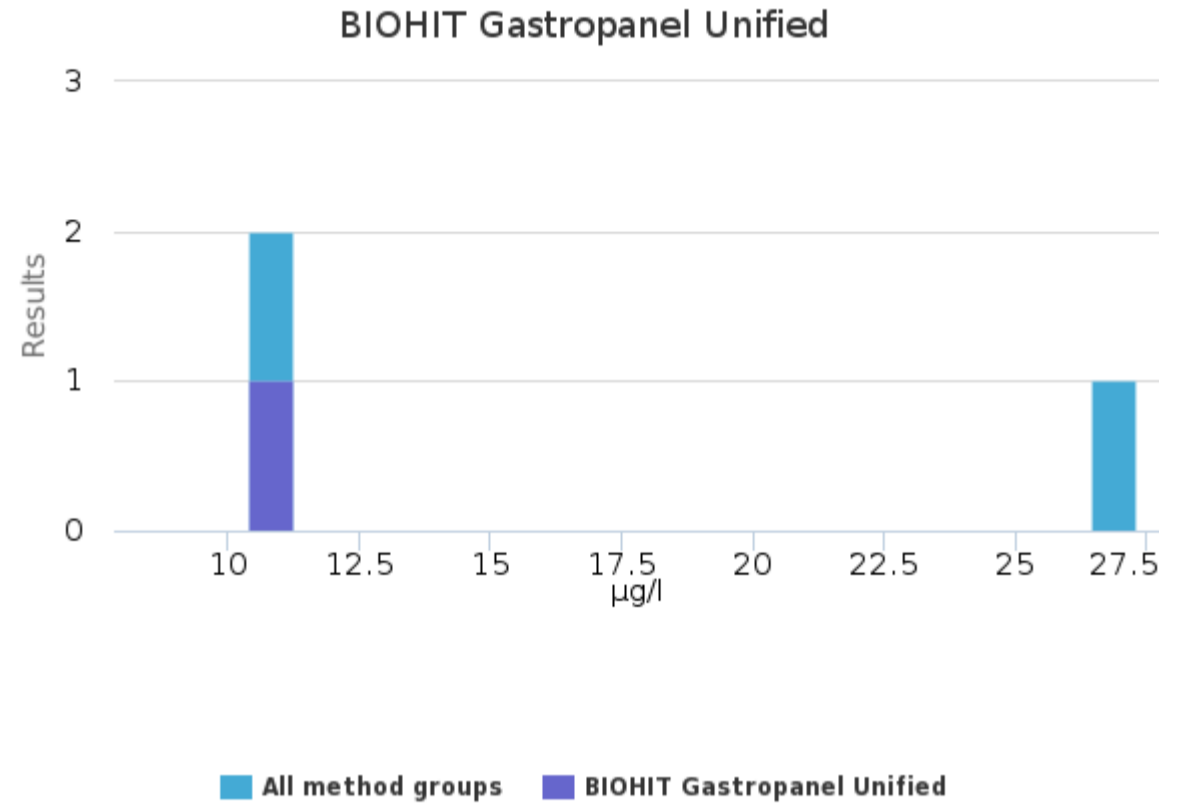
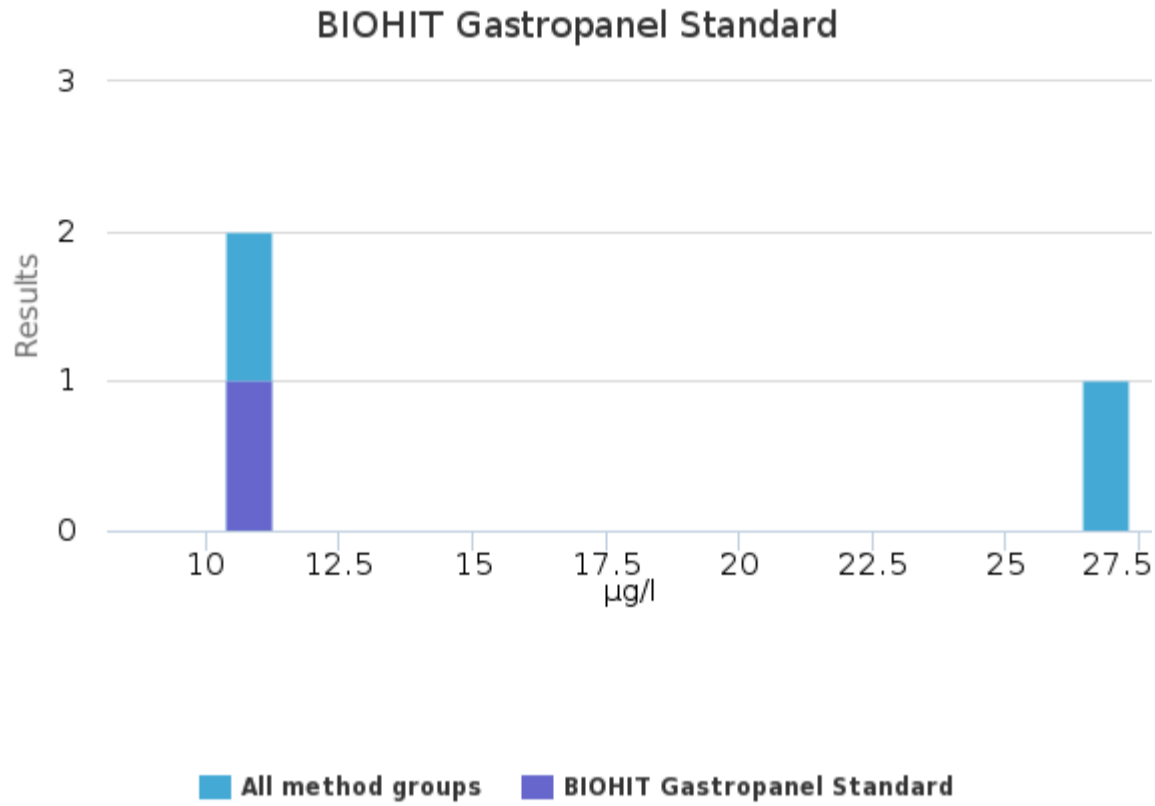
Sample S001 | Pepsinogen I, µg/l| histogram summaries in LabScala



Sample S001 | Pepsinogen II, µg/l

Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
BIOHIT Gastropanel Standard	-	-	-	-	-	10.80	10.80	-	1
BIOHIT Gastropanel Unified	-	-	-	-	-	10.40	10.40	-	1
DIASource Pepsinogen ELISA	-	-	-	-	-	27.30	27.30	-	1
All	16.17	10.80	9.64	59.7	5.57	10.40	27.30	-	3

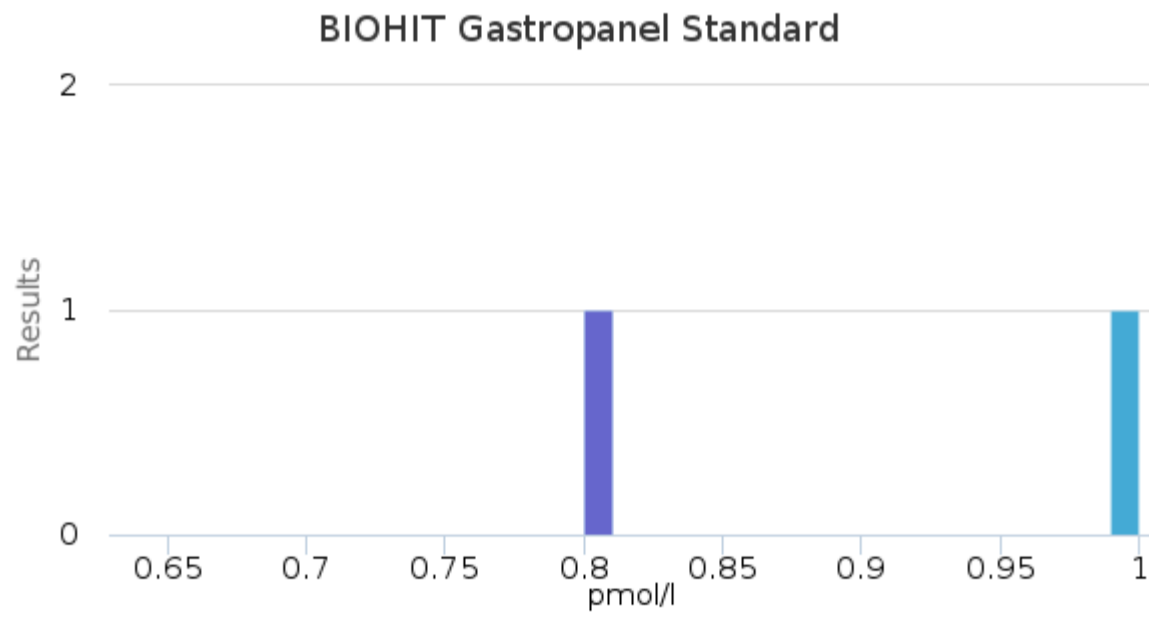
Sample S001 | Pepsinogen II, µg/l| histogram summaries in LabScala



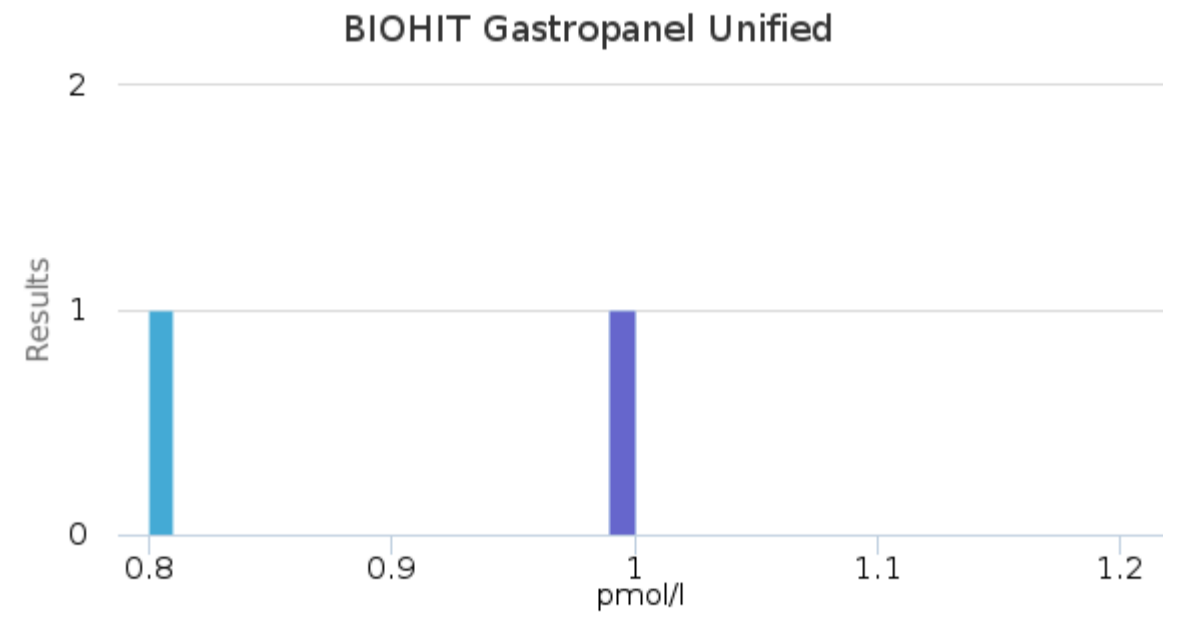
Sample S001 | Gastrin-17, pmol/l

Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
BIOHIT Gastropanel Standard	-	-	-	-	-	0.80	0.80	-	1
BIOHIT Gastropanel Unified	-	-	-	-	-	1.00	1.00	-	1
All	0.90	0.90	0.14	15.7	0.10	0.80	1.00	-	2

Sample S001 | Gastrin-17, pmol/l | histogram summaries in LabScala



■ All method groups ■ BIOHIT Gastropanel Standard

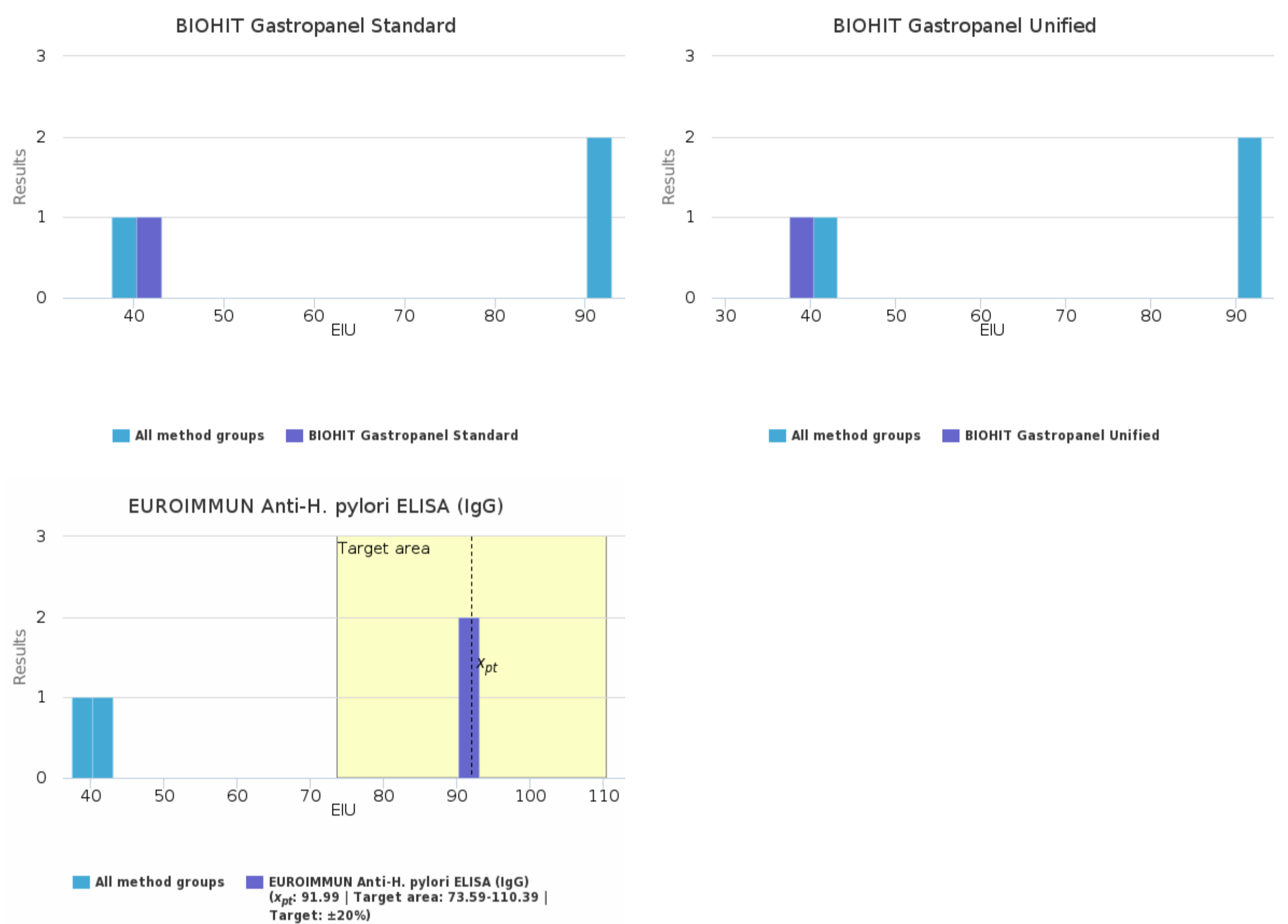


■ All method groups ■ BIOHIT Gastropanel Unified

Sample S001 | Helicobacter pylori Ab, EIU

Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
BIOHIT Gastropanel Standard	-	-	-	-	-	42.30	42.30	-	1
BIOHIT Gastropanel Unified	-	-	-	-	-	37.55	37.55	-	1
EUROIMMUN Anti-H. pylori ELISA (IgG)	91.99	91.99	1.40	1.5	0.99	91.00	92.98	-	2
All	65.96	66.65	30.13	45.7	15.07	37.55	92.98	-	4

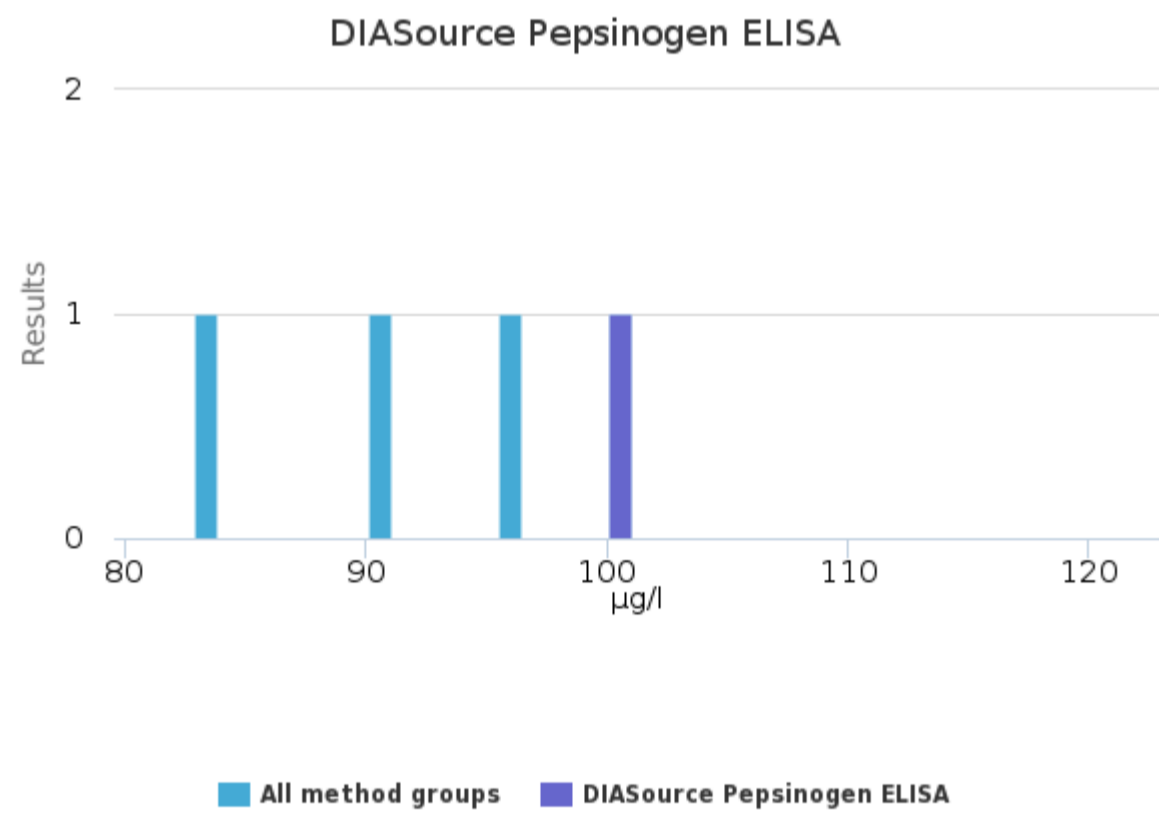
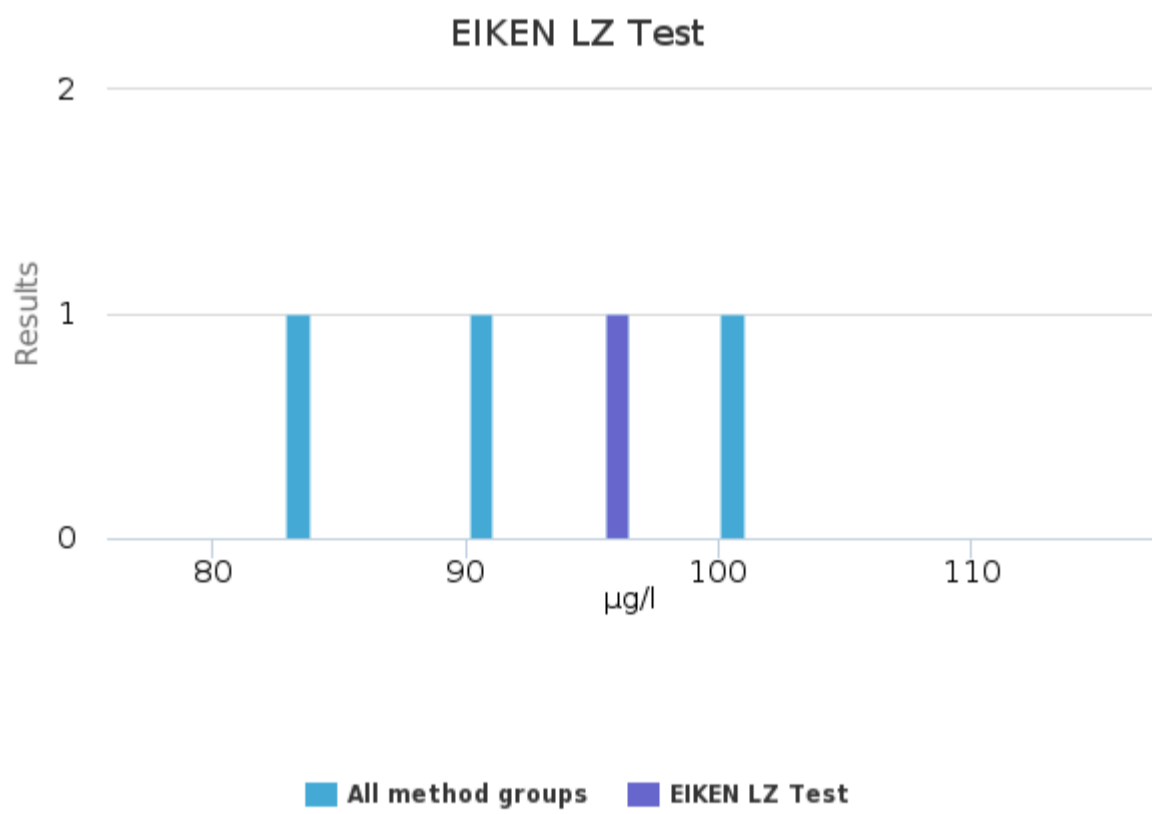
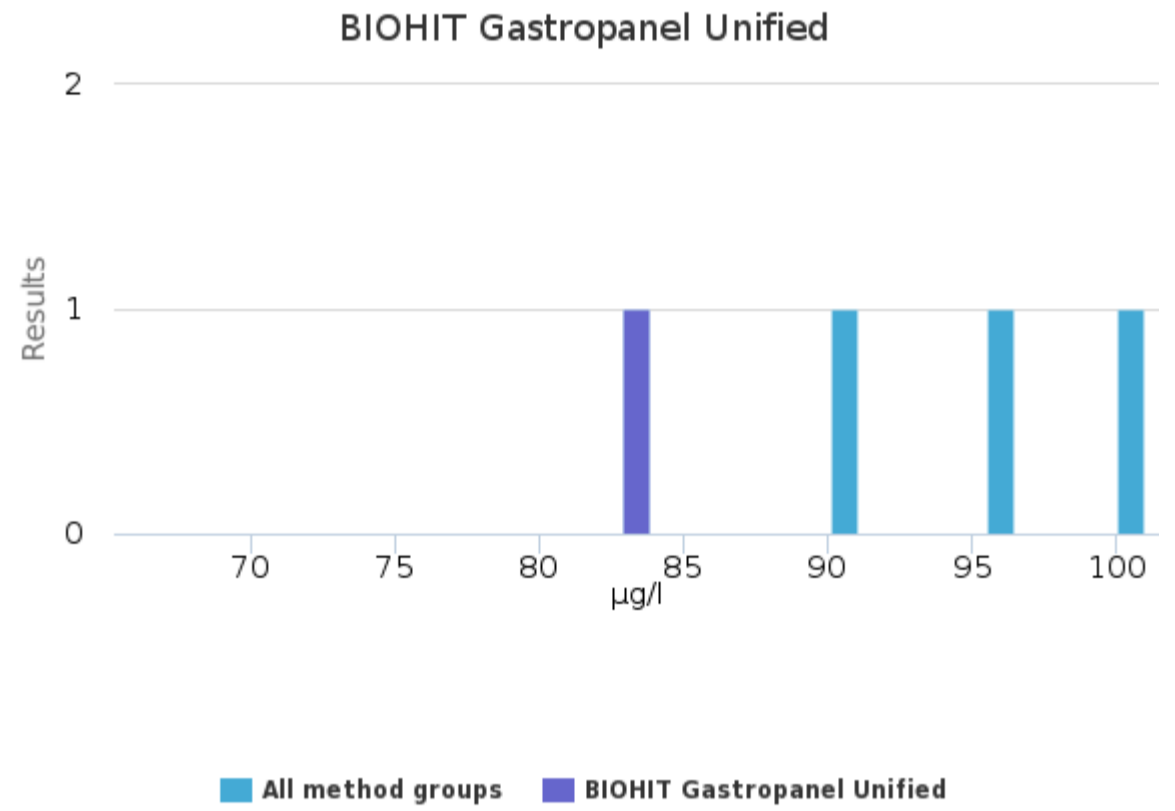
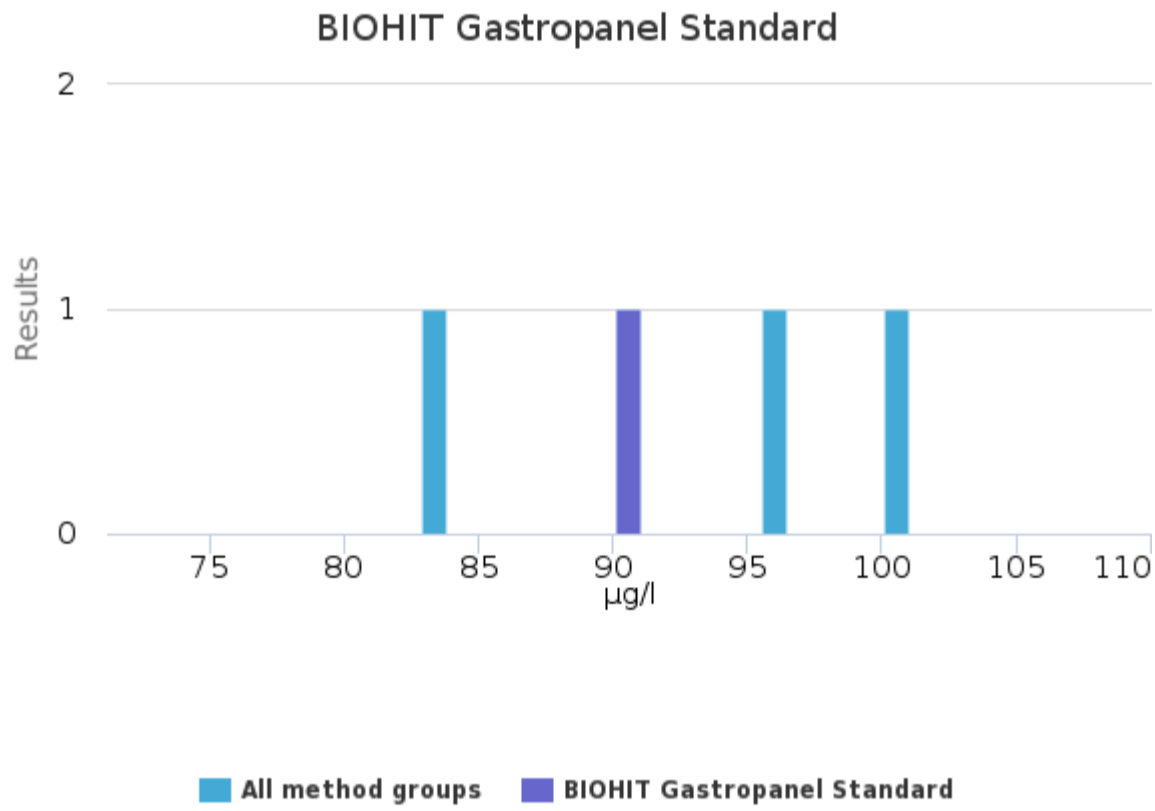
Sample S001 | Helicobacter pylori Ab, EIU | histogram summaries in LabScala



Sample S002 | Pepsinogen I, µg/l

Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
BIOHIT Gastropanel Standard	-	-	-	-	-	90.40	90.40	-	1
BIOHIT Gastropanel Unified	-	-	-	-	-	82.92	82.92	-	1
EIKEN LZ Test	-	-	-	-	-	96.25	96.25	-	1
DIASource Pepsinogen ELISA	-	-	-	-	-	101.00	101.00	-	1
All	92.64	93.33	7.80	8.4	3.90	82.92	101.00	-	4

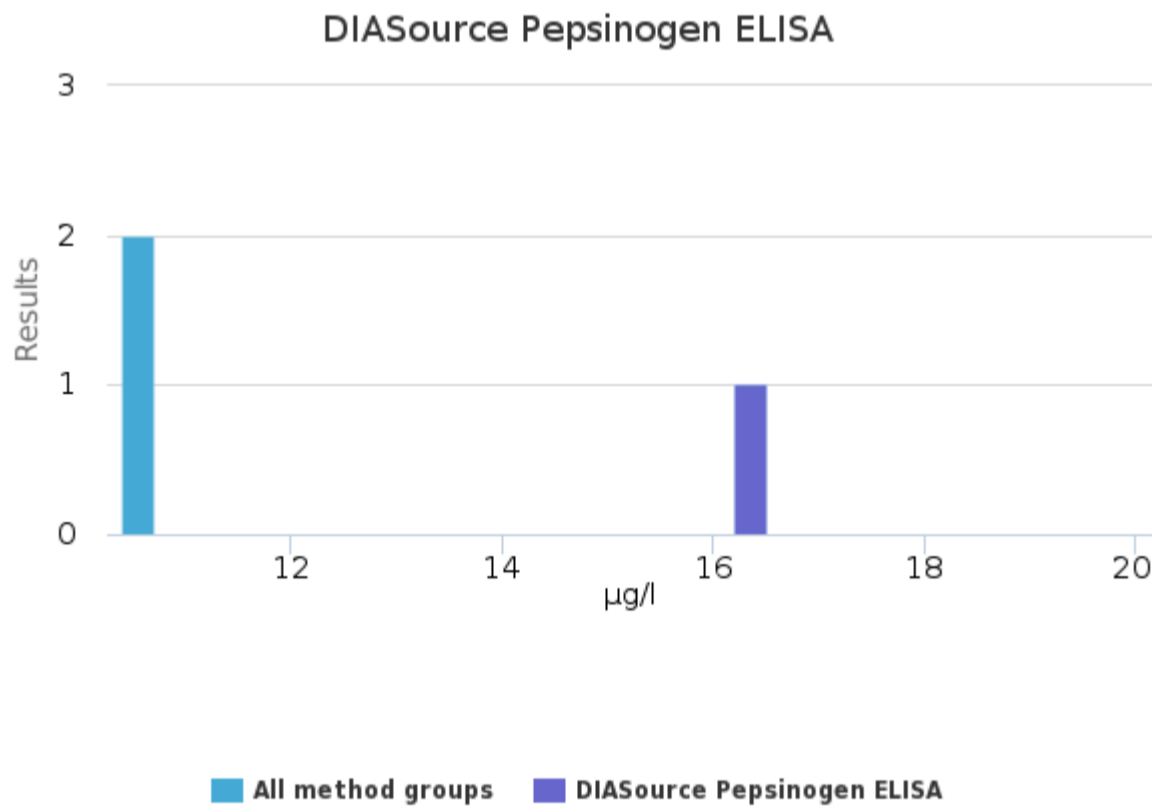
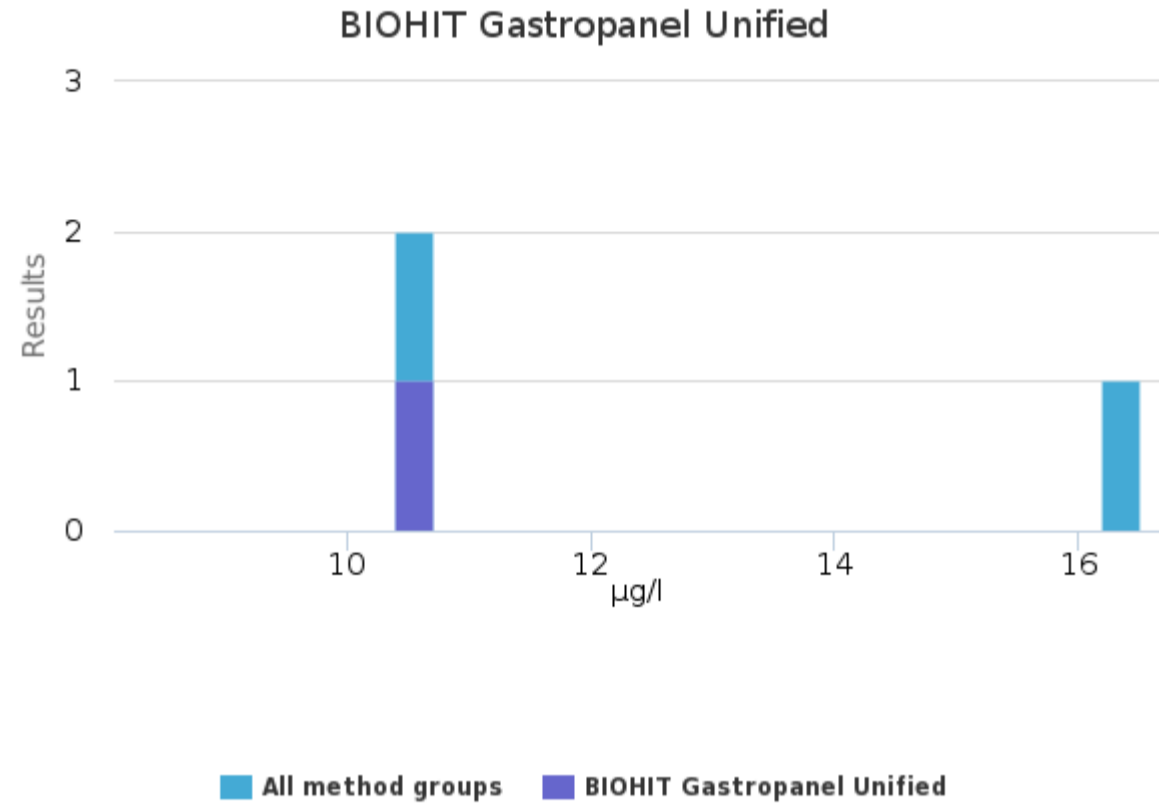
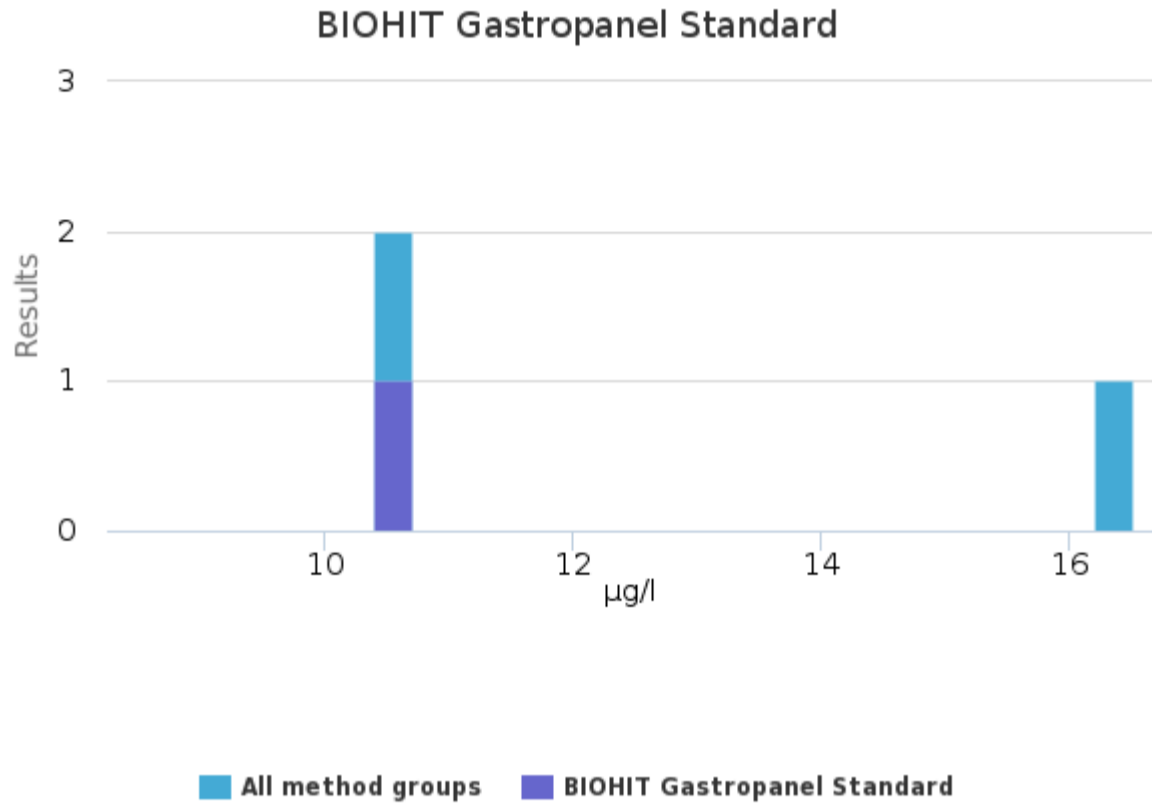
Sample S002 | Pepsinogen I, µg/l| histogram summaries in LabScala



Sample S002 | Pepsinogen II, µg/l

Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
BIOHIT Gastropanel Standard	-	-	-	-	-	10.60	10.60	-	1
BIOHIT Gastropanel Unified	-	-	-	-	-	10.40	10.40	-	1
DIASource Pepsinogen ELISA	-	-	-	-	-	16.50	16.50	-	1
All	12.50	10.60	3.47	27.7	2.00	10.40	16.50	-	3

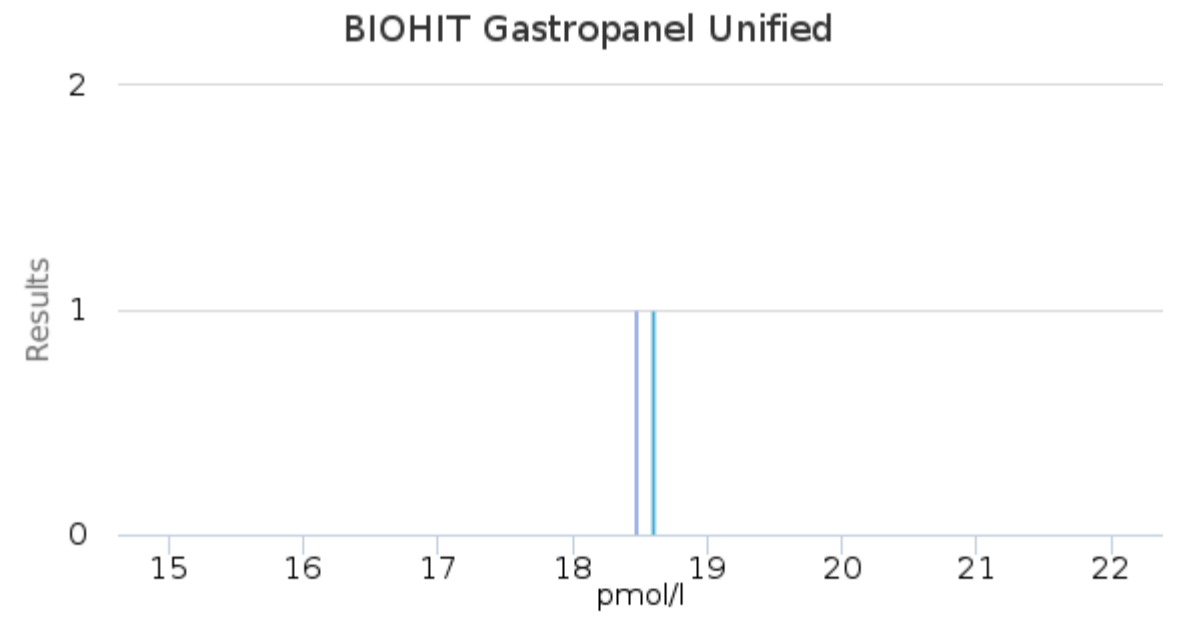
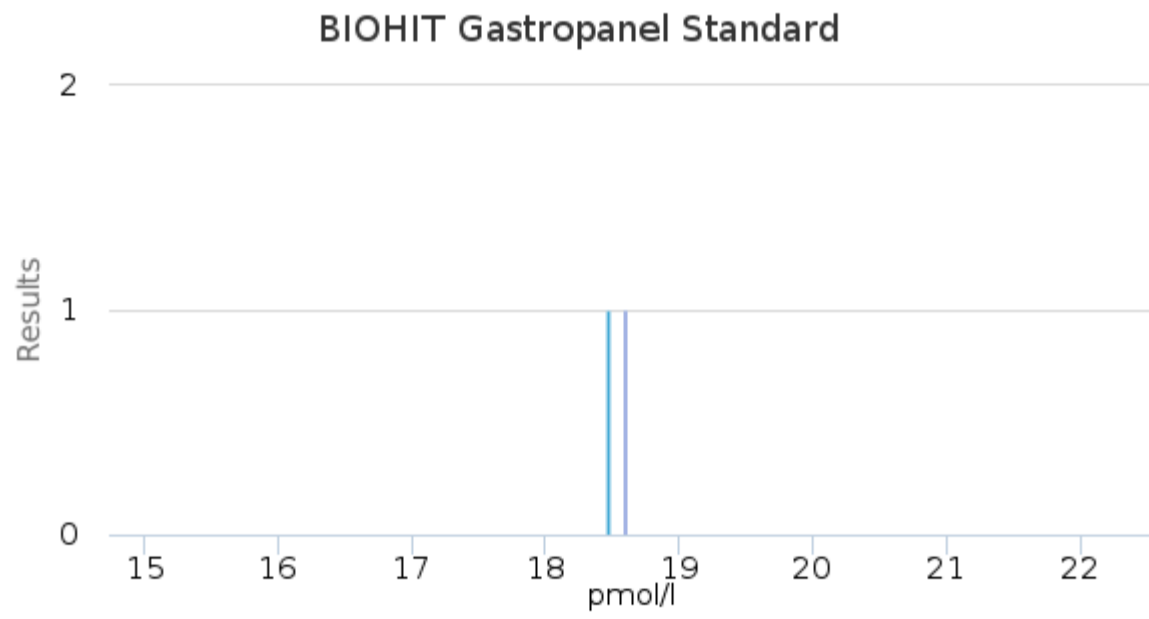
Sample S002 | Pepsinogen II, µg/l | histogram summaries in LabScala



Sample S002 | Gastrin-17, pmol/l

Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
BIOHIT Gastropanel Standard	-	-	-	-	-	18.60	18.60	-	1
BIOHIT Gastropanel Unified	-	-	-	-	-	18.46	18.46	-	1
All	18.53	18.53	0.10	0.5	0.07	18.46	18.60	-	2

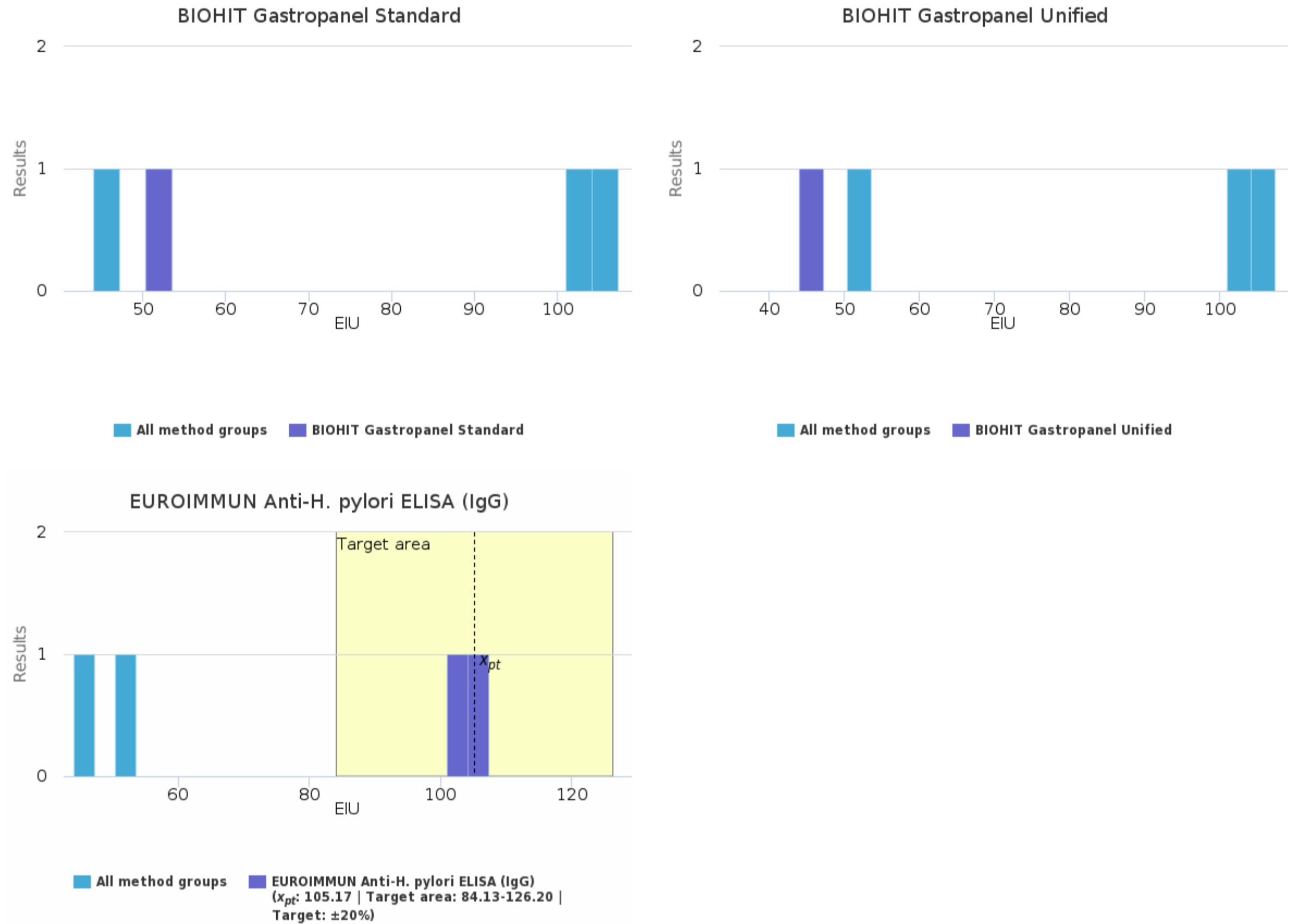
Sample S002 | Gastrin-17, pmol/l | histogram summaries in LabScala



Sample S002 | Helicobacter pylori Ab, EIU

Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
BIOHIT Gastropanel Standard	-	-	-	-	-	53.00	53.00	-	1
BIOHIT Gastropanel Unified	-	-	-	-	-	44.03	44.03	-	1
EUROIMMUN Anti-H. pylori ELISA (IgG)	105.17	105.17	3.06	2.9	2.17	103.00	107.33	-	2
All	76.84	78.00	32.96	42.9	16.48	44.03	107.33	-	4

Sample S002 | Helicobacter pylori Ab, EIU | histogram summaries in LabScala



Sample S001 | Is the clinical interpretation done by using a software?

Is the clinical interpretation done by using a software?	Total
Yes, GastroSoft software	2
No software was used	3
Total	5

Sample S001 | Clinical interpretation

Clinical interpretation	Total
Laboratory does not give clinical interpretation	3
There is no atrophic gastritis in the corpus of the stomach mucosa. The results indicate atrophic gastritis of the antrum due to a Helicobacter pylori infection.	2
Total	5

Sample S002 | Is the clinical interpretation done by using a software?

Is the clinical interpretation done by using a software?	Total
Yes, GastroSoft software	2
No software was used	2
Total	4

Sample S002 | Clinical interpretation

Clinical interpretation	Total
Laboratory does not give clinical interpretation	3
The results indicate a Helicobacter pylori infection. There is no atrophic gastritis of the stomach mucosa.	1
The results indicate a Helicobacter pylori infection. Elevated pepsinogen and/or gastrin-17 levels may indicate low acid output e.g., due to medication that inhibits acid secretion.	1
Total	5

External Quality Assessment Scheme

Gastric biomarkers Round 1, 2022

Specimens

Sample S001 (LQ751722011) and sample S002 (LQ751722012) were lyophilized human serum samples.

Based on the previous tests and the results of this round, the samples are homogeneous, stable, and suitable for the external quality assessment scheme.

The materials were sent without temperature control packaging.

Report info

It is important to read the Final report first, because it contains important information of the samples and results in each round.

Your own result should be compared to others using the same method. Assigned values (xpt, target values) are means of the results where results deviating more than ± 3 standard deviation from the median are removed. The standard uncertainty (u) of the assigned value is reported as standard error of the mean (SEM). Additionally, if the measurement uncertainty of the target value is large an automatic text is printed on the report: "The uncertainty of the assigned value is not negligible, and evaluations could be affected." In case the client's result is the only one in the method group, no assigned value will be calculated, no target area shown, and no statistics calculated. In case there are only a few results in the client's own method group, the result can be compared to all method mean or to a group that is similar to the own method. Results reported with $<$ or $>$ -signs cannot be included in the statistics.

For information on report interpretation and performance evaluation, please see the "EQAS Interpretation guidelines" LabScala User instructions (top right corner? Help link).

Comments – EQA coordinator

General

Five clients from four countries participated on the round. This scheme was intended for methods that measure gastrin-17 and other gastric biomarkers and provide a clinical interpretation of Helicobacter pylori infection and gastric antrum or corpus atrophy. There were two clients who did not report all analytes nor the clinical interpretation and therefore did not receive all possible benefits of the round.

Gastrin is present in 34 amino acids (G34) in the form of big gastrin and 17 amino acids (G17) in forms of little gastrin, of which there are even more subforms. Depending on the assay method, different forms may be immunoreactive and become measurable. Most of the gastrin measured in the circulation is usually in the G17 form. One out of three clients reported a gastrin result using a method that measures total gastrin and not gastrin-17. Thus, results of both samples differed significantly from the other results and were manually excluded from the statistics.

Quantitative results

In sample 001, gastrin-17, pepsinogen I and II concentrations were within the clinical reference range, but helicobacter antibodies were elevated. The results of all but one participant (Pepsinogen II analyzed by Diasource) were consistent. In sample 002, Pepsinogen I and II concentrations were within the

2022-07-05

FINAL REPORT

Product no. 2753

Samples sent	2022-06-06
Round closed	2022-07-01
Final report	2022-07-05

Request for correction

Typing errors in laboratory's result forms are on laboratory's responsibility. Labquality accepts responsibility only for result processing. Requests must be notified by writing within three weeks from the date of this letter.

Authorized by

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clinical reference range (except pepsinogen II analyzed by Diasource) whereas gastrin-17 and helicobacter antibodies were elevated.

Clinical interpretation

In the summary report and client specific reports the consensus result is marked with a green background. Laboratory's own result is marked with a radio button. Two clients out of the five used Gastrosoft to make a clinical diagnosis, while the other participants did not.

The patient case for sample S001 was a protein-stimulated blood sample from a 70-year-old old woman with epigastric pain and postprandial symptoms for 14 months. Manifests also iron-deficiency anemia. No previous eradication of H. pylori, no PPI medication, occasional use of NSAIDs. The Gastrosoft users had the clinical interpretation "There is no atrophic gastritis in the corpus of the stomach mucosa. The results indicate atrophic gastritis of the antrum due to a Helicobacter pylori infection". Both clients had used Biohit reagents and Gastrosoft and reported same clinical interpretation for sample S001.

The patient case of sample S002 was a fasting blood sample from a 66-year-old man with dyspeptic pain for three years. No previous eradication of H. pylori, use of PPI medication, but now a 5- day break, occasional use of NSAIDs. One client had the clinical interpretation "The results indicate a Helicobacter pylori infection. There is no atrophic gastritis of the stomach mucosa." and the other "The results indicate a Helicobacter pylori infection. Elevated pepsinogen and/or gastrin-17 levels may indicate low acid output e.g., due to medication that inhibits acid secretion." Both clients had used Biohit reagents and Gastrosoft and still had different clinical interpretations.

The quantitative results of all participants should lead to the same clinical interpretation. The difference in interpretations may be caused if the background information is not considered when using Gastrosoft. This highlights the importance of including provided patient data when interpreting the results.

In conclusion, there were very view results on the round and peer group comparisons could be made only for H-Pylori Ab in the Eiken method group which had two results. Participants are encouraged to report results of all analytes and the clinical interpretation to receive all benefits of this EQA round. Please register to the two Gastric biomarkers rounds that will be arranged in 2022. For questions, please contact the EQA coordinator or Labquality's customer service at info@labquality.fi .

End of report

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